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FILING DATE ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. FIRST NAMED INVENTOR 10/014,147 12/07/2001 Frank Blecha 23625-DIV1 7389 **EXAMINER** 7590 06/18/2004 Tracey S. Truitt LUKTON, DAVID Suite 400 **ART UNIT** PAPER NUMBER 2405 Grand Boulevard Kansas City, MO 64108 1653

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	10/014,147	BLECHA ET AL.
	Examiner	Art Unit
	David Lukton	1653
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SiX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
 Responsive to communication(s) filed on <u>23 September 2003</u>. This action is FINAL. 2b) This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213. 		
Disposition of Claims		
 4) Claim(s) 1-11 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-11 are subject to restriction and/or election requirement. 		
Application Papers		
 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. 		
Priority under 35 U.S.C. § 119		
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 		
Attachment(s)		
 Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 	4) Interview Summary (Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:	•

A restriction is imposed. First, however, the following subgenera are defined:

- G1: the peptide used for administering or contacting has a sequence which conforms to the following formula: X_1 -p- X_2 -P-p- X_3 -P
- G2: the peptide used for administering or contacting has a sequence which conforms to the following formula: X_3 -P-p- X_2 -P-p- X_1 .
- G3: Within the formula " X_1 -p- X_2 -P-p- X_3 -P" and " X_3 -P-p- X_2 -P-p- X_1 ,", a lowercase "p" refers to proline.
- G4: Within the formula " X_1 -p- X_2 -P-p- X_3 -P" and " X_3 -P-p- X_2 -P-p- X_1 ", a lowercase "p" refers to an entity other than proline.
- G5: the administered peptide can be whatever the claims permit, provided that G1 and G2 are excluded.
- G6: The administered peptide is limited to G1 or G2

Restriction to one of the following inventions is required under 35 U.S.C. §121:

- 1. Claims 1-8, drawn to a method of attracting a leukocyte by administering a peptide which is limited to subgenus G6
- 2. Claims 1-8, drawn to a method of attracting a leukocyte by administering a peptide which is limited to subgenus G5
- 3. Claims 9-11, drawn to a method of inhibiting leukocyte superoxide production by contacting a leukocyte with a peptide that is limited to G1 and G3
- 4. Claims 9-11, drawn to a method of inhibiting leukocyte superoxide production by

contacting a leukocyte with a peptide that is limited to G2 and G3

5. Claims 9-11, drawn to a method of inhibiting leukocyte superoxide production by contacting a leukocyte with a peptide that is limited to G6 and G4.

The claimed inventions are distinct.

The first point concerns subgenus G4. Within the formulas (" X_1 -p- X_2 -P-p- X_3 -P" and " X_3 -P-p- X_2 -P-p- X_1 -"), lowercase "p" is undefined. One can infer from page 17, lines 23+ that lowercase "p" represents proline, but perhaps refers to a "non-critical" (proline) contact residue. But applicants may reveal at a later time that lowercase "p" has some other meaning. Since lowercase "p" is not defined, subgenus G4 has been created. In the event that "p" is intended to refer to proline, Group 5 may be disregarded. On the other hand, in the event that applicants choose to elect Group 5, applicants should supply a definition of lowercase "p".

Groups 1 and 2 have been created on the basis of whether the formulas recited in claim 9 may be invoked. The creation of the two subgenera for claims 1-8 should not, however, be taken as an indication that a determination has been made with regard to description/ new matter. In fact, the examiner would opine at this point that introduction of either subgenus G1 or G2 (or the exclusion thereof) into claim 1 would constitute new matter. However,

applicants may choose to assert that introduction of either subgenus G1 or G2 (or the exclusion thereof) into claim 1 would <u>not</u> constitute new matter. In the event that such an assertion were to be made, and in the further event that Group I were modified to recite (or exclude) G1 or G2, the restriction between Group 1 and Group 2 would then arise (otherwise, the restriction between Group 1 and Group 2 will most likely be moot).

Thus, although five different groups are recited, two of them are likely to be "null" or "moot". In addition, in the event that Group 3 is elected, and claims therein found allowable, the possibility of rejoining Group 4 is not necessarily precluded. Similarly, in the event that Group 4 is elected, and claims therein found allowable, the possibility of rejoining Group 3 is not necessarily precluded.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that one of Groups 1 or 2 is chosen for initial examination, the species to be

elected are as follows:

- (a) a specific peptide which is to be administered;
- (b) a specific location to which the leukocyte is to be attracted;
- (c) a specific type of leukocyte (e.g., neutrophil, eosinophil, or mononuclear phagocyte)

In the event that one of Groups 3-5 is chosen for initial examination, election of (a) a specific peptide which is to be contacted with the leukocyte is required, and (b) a specific type of leukocyte (e.g., neutrophil, eosinophil, or mononuclear phagocyte)

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at 571-272-0951. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

PATENT EXAMPLES

SHOUP 1808